IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No:	10/798,786
Appellant:	Robert A. Van Tassel et al.
Filed:	March 10, 2004
Title:	METHODS FOR TREATMENT OF ANEURYSMS
T.C./A.U.:	3739
Examiner:	Roy Dean Gibson
Confirmation No.:	5624
Docket No.:	BSI-557US1 (formerly ENDOV-67986)

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby request reconsideration and reversal of the Final Rejection dated November 28, 2006, and the Advisory Action dated February 21, 2007, of claims 61-66, 68-71 and 73.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken or within two months from the date of the Notice of Appeal, whichever is later.

The fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2), together with any extension fee required in connection with the filing of this Brief, are provided herewith.

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I. REAL PARTY IN INTEREST

The real party in interest is Endovascular Technologies, Inc., the assignee of record, which is a subsidiary of Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Upon entry of the Amendment Under 37 C.F.R. 41.33 submitted herewith, claims 1-60 and 72 are cancelled. While the November 28, 2006 Final Office Action indicates that claim 1 is pending, such is in error as claim 1 was canceled in Appellants July 15, 2004 Supplemental Preliminary Amendment and has been listed as canceled in each subsequent response filed by Appellants. Furthermore, the patentability of claim 1 has not been addressed in any office action.

Claims 61-71 and 73 are pending. Claims 67 and 72 were objected to, however, claim 67 has been amended into independent form and the subject matter of claim 72 has been added to independent claim 69. Claims 67 and 69 should now be in condition for allowance. Claims 70, 71 and 73 depend from claim 69 and should also now be in condition for allowance. Claims 61-66 and 68 stand finally rejected. Claims 61-66 and 68 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

An amendment subsequent to the Final Rejection was filed on January 25, 2007. While such amendment canceled rejected claims 51-60 and amended claim 69 to include the subject matter of allowable claim 72, the amendment was not entered. Appellants are filing concurrently herewith an Amendment Under 37 C.F.R. 41.33 to cancel claims 51-60, to amend claim 67 into independent form and amend claim 69 to include the subject matter of allowable claim 72.

V. SUMMARY OF CLAIMED SUBJECT MATTER

As set forth in the specification at page 5, line 23 through page 6, line 17, in one aspect, "the invention pertains to a method for increasing the adventitial mass of a blood vessel wall within a target region by administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial layer, and irradiating a target region of the blood vessel wall so that the photoactivatable agent is activated to increase the adventitial volume.

In another aspect, the invention pertains to a method for treating an aneurysm by increasing the adventitial volume of a blood vessel by administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial region of the blood vessel, and irradiating the site of the aneurysm so that the photoactivatable agent increases the adventitial volume.

Strengthening a vessel wall of a subject by increasing the volume of at least one layer of the blood vessel wall may also be attained by irradiating the target region with light energy of a specific wavelength. The irradiation alone can be sufficient to activate cellular and molecular process that result in an increase in a vessel wall layer.

Accordingly, in another aspect, the invention pertains to a method for strengthening a vessel wall of a subject by irradiating a target region with UVC irradiation, so that the UVC irradiation induces a structural change in at least one layer of the vessel wall. Additionally, the invention pertains to a method for increasing the adventitial volume of a blood vessel wall by irradiating the target region with UVC irradiation, and more specifically, to a method for treating an aneurysm by increasing the adventitial volume of a blood vessel by irradiating the site of the aneurysm with UVC irradiation."

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 61-63, 65 and 66 are unpatentable under 35 U.S.C. § 102(a) as anticipated by U.S. Patent No. 5,913,884 (Trauner et al.).

B. Whether claims 61-66 and 68 are unpatentable under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,488,673 (Laufer et al.).

VII. ARGUMENT

A. Rejection Under 35 U.S.C. §102(a) Over U.S. Patent No. 5,913,884

Claims 61-63, 65, 66 and 68 stand rejected under 35 U.S.C. § 102(a) as anticipated by U.S. Patent No. 5,913,884 (Trauner et al.). It is respectfully submitted, however, that the pending claims are patentable over Trauner et al. for at least the reasons set forth below.

Anticipation requires that each and every limitation of the claim be disclosed, either expressly or under principles of inherency, in a single prior art reference. *In re* Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Absence from the reference of any claimed limitation negates anticipation. *Rowe v. Dror*, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

Independent claim 61 recites:

"A method for increasing an adventitial area of tissue comprising:

administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial area of a target tissue;

applying energy to the target tissue to react within the photoactivatable agent; and

increasing an adventitial area in the area of the target tissue."

The Final Office Action indicates on page 2 that "administering a photoactivatable agent to a subject as disclosed by Trauner et al., inherently results in the agent being taken up by an adventitial area of a blood vessel which inherently results in increasing the adventitial area."

As set forth in M.P.E.P. §2112, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." "In relying upon the theory of

inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). In Ex parte Levy, the Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.

The Final Office Action does not include a basis in fact and/or technical reasoning to reasonably support that the disclosure of Trauner et al. inherently results in the agent being taken up by an adventitial area of a blood vessel which inherently results in increasing the adventitial area.

To the contrary, Trauner et al. explains at column 2, lines 27-29, that "the modulation can include inhibiting fibrosis by administering a high dose of photodynamic therapy." (emphasis added). As explained at column 2, line 60 to column 3, line 3,

> [a]s used herein, 'low dose' photodynamic therapy means a dose sufficient to kill from 0% to about 10% of all cells exposed to the photoactiviting light if the photosensitizer is untargeted, or from 0% to about 10% of the targeted cells exposed to the photoactiviting light, if the photosensitizer is targeted. As used herein, 'high dose' photodynamic therapy means a dose sufficient to kill from about 10% to about 90% of all cells exposed to the photoactivating light if the photosensitizer is untargeted, or from about 10% to about 90% of the targeted cells exposed to the photoactivating light, if the photosensitizer is targeted.

Trauner et al. teaches that a low dose therapy targets only a small percentage of cells, i.e. 10% or less of the cells, and therefore, it is not inherent that the agent would be taken up in the adventitial area nor that such would inherently result in increasing the adventitial area. If a high dose therapy were utilized, such would result in an inhibiting of fibrosis.

Since Trauner et al. does not disclose every limitation of the claimed invention, either expressly or inherently, the claimed invention is not anticipated

thereby. Appellants respectfully request reconsideration and reversal of the rejection of claims 61-63, 65 and 66 under 35 U.S.C. §102(a).

B. Rejection Under 35 U.S.C. §102(e) Over U.S. Patent No. 6,488,673

Claims 61-66 and 68 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,488,673 (Laufer et al.). It is respectfully submitted, however, that the pending claims are patentable over Laufer et al. for at least the reasons set forth below.

Anticipation requires that each and every limitation of the claim be disclosed, either expressly or under principles of inherency, in a single prior art reference. *In re* Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Absence from the reference of any claimed limitation negates anticipation. *Rowe v. Dror*, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

Independent claim 61 recites:

"A method for increasing an adventitial area of tissue comprising:

administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial area of a target tissue;

applying energy to the target tissue to react within the photoactivatable agent; and

increasing an adventitial area in the area of the target tissue."

The Final Office Action indicates on page 3 that "Laufer et al. disclose a method of applying heat to the inner wall of a vessel which inherently heats the outermost connective tissue of the vessel (adventitial area of the tissue) essentially as claimed. . . ." (emphasis added).

The Final Office Action acknowledges that Laufer et al. teaches applying heat to the inner wall. The Final Office Action does not include a basis in fact and/or technical reasoning to reasonably support that the heating of the inner wall

inherently heats the outermost connective tissue of the vessel (adventitial area of the tissue).

As set forth in M.P.E.P. §2112, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). In Ex parte Levy, the Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.

As explained above, Trauner et al., which is also of record, explains that a high dose of therapy will inhibit fibrosis. Taking the complete teachings of the cited prior art references, the suggested heating to an extent necessary to heat from the inside surface to the outer surface, would likely result in inhibition of fibrosis, not "increasing an adventitial area in the area of the target tissue" as recited in claim 61.

Since Laufer et al. does not disclose every limitation of the claimed invention, either expressly or inherently, the claimed invention is not anticipated thereby. Appellants respectfully request reconsideration and reversal of the rejection of claims 61-66 and 68 under 35 U.S.C. §102(e).

Accordingly, for at least the above reasons, appellants respectfully contend that independent claims 61, 67 and 69 and dependent claims 62-66, 68, 70, 71 and 73 of this application are now in condition for allowance. Accordingly, appellants respectfully request reversal of the Final Rejection.

Respectfully Submitted,

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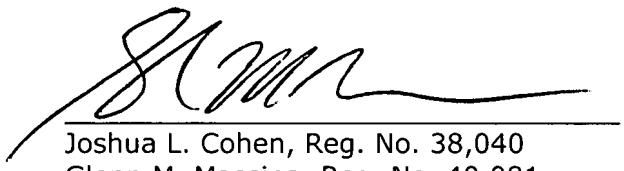

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Enclosures: Claims Appendix
Evidence Appendix
Deleted Proceedings Appendix

Dated: August 28, 2007

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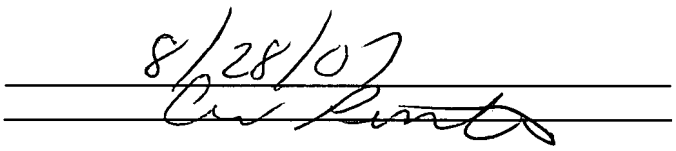

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CLAIMS APPENDIX

1-60. (Canceled)

61. A method for increasing an adventitial area of tissue comprising:

administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial area of a target tissue;

applying energy to the target tissue to react within the photoactivatable agent; and

increasing an adventitial area in the area of the target tissue.

62. The method of claim 61, wherein the step of administering a therapeutically effective amount of a photoactivatable agent further comprises systemically administering the photoactivatable agent.

63. The method of claim 61, wherein the step of administering a therapeutically effective amount of a photoactivatable agent further comprises locally administering the photoactivatable agent.

64. The method of claim 61, wherein the step of administering a therapeutically effective amount of a photoactivatable agent further comprises administering a psoralen agent or derivatives thereof.

65. The method of claim 61, wherein the step of applying energy to the target tissue further comprises irradiating the target tissue internally using a light delivery catheter.

66. The method of claim 65, wherein the step of applying energy to the target tissue further comprises irradiating the target tissue using a light delivery catheter without occluding fluid flow.

67. A method for increasing an adventitial area of tissue comprising:

administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial area of a target tissue;

applying energy to the target tissue to react within the photoactivatable agent; and

increasing an adventitial area in the area of the target tissue, wherein the step of applying energy to the target tissue further comprises irradiating the site of an aneurysm externally using an external light delivery source.

68. The method of claim 61, wherein the step of applying energy to the target tissue further comprises irradiating the target tissue with UV irradiation.

69. A method for treating tissue of a subject comprising,

applying an agent and irradiating a target region of tissue with UVC irradiation to accomplish an interaction between the agent and the UVC irradiation; and

inducing fibrosis or increasing an adventitial layer in at least one layer of the tissue;

wherein the step of irradiating the target region further comprises irradiating the target region externally using an external light delivery source.

70. The method of claim 69, wherein the step of irradiating the target region further comprises irradiating the target region internally using a light delivery catheter.

71. The method of claim 70, wherein the step of irradiating the target region further comprises irradiating the target region internally using a light delivery catheter without occluding fluid flow.

72. (Canceled)

73. The method of claim 69, wherein the step of irradiating the target region further comprises irradiating the target region with UVC irradiation having a wavelength of about 240 to 370 nanometers.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None